Health Information Technology Standards Committee
DRAFT
Summary of the April 18, 2012, Meeting

KEY TOPICS

1. Call to Order
Mary Jo Deering, Office of the National Coordinator (ONC), welcomed participants to the 35th meeting of the HIT Standards Committee (HITSC). She reminded the participants that this was a Federal Advisory Committee meeting, with an opportunity for the public to make comments, and that a summary of the meeting would be available online. She conducted roll call, and turned the meeting over to HITSC Chair Jonathan Perlin.

2. Opening Remarks
Perlin said that the work the Committee would be doing today would serve as a lens to consider how to develop a set of standards for Meaningful Use Stage 3. He welcomed MacKenzie Robertson, who will soon be taking over Mary Jo Deering's duties at ONC, to her first face-to-face HITSC meeting. He also acknowledged Deering's efforts.

Perlin asked the Committee for additions or amendments to the minutes of last month's meeting. Jamie Ferguson indicated that he would submit a few typographical corrections. Otherwise, the minutes were approved.

> **Action Item #1:** The Committee approved the minutes of the March 27, 2012 HITSC meeting by consensus.

3. Review of the Agenda
Perlin explained that the Committee would approach the day's activities by tackling the Notice of Proposed Rulemaking (NPRM) chapter and verse. Each Workgroup Chair would briefly discuss his or her group's findings for each of the NPRMs sections. The work today will be possible because the ONC created a grid to allow the Committee and others to view multiple inputs simultaneously.

Perlin reminded the group that their purview is standards; only to the extent that policy affects standards will it be appropriate for discussion in this venue. He introduced HITSC Vice Chair John Halamka, who would lead the group through the grid.

4. Comments
Halamka explained that they would be producing a recommendation letter at the end of this process, and so the plan was to review each sub-section in turn, checking each off and handing it to ONC's Steve Posnak, one by one. He said there was great internal consistency across the Workgroups, and he expected little controversy. He noted that yesterday CMS published 11 pages of corrections to the NPRM.

There are some issues and questions that the ONC wanted to hear discussion on that are outside of specific NPRM sub-sections; those issues will be taken up after they have covered the NPRM's sub-sections. Following these remarks, Halamka began the group discussion.

5. Discussion of Workgroup Comments on Standards & Certification Criteria Notice of Proposed Rulemaking (NPRM)

The Committee touched on each section of the NPRM. Significant discussions were centered in certain areas, as follows:

Electronic Prescribing

Jamie Ferguson said that the Clinical Operations Workgroup heard concern from a number of members about the fact that HL7 was not mentioned. Obviously the National Council for Prescription Drug Programs (NCPDP) script standard should be used, particularly in reference to discharge e-prescribing and hospital-filled medication orders. They heard from a number of organizations that are doing business as organized health care arrangements under Health Insurance Portability and Accountability Act (HIPAA). Their reading is that they would have to switch to NCPDP inside the hospital. Last year they revisited this issue, Ferguson said. They consulted with the National Institute of Standards and Technology (NIST), and went through certification testing analysis of HL7 Version 2. NIST found that it was easy to identify for testing purposes any valid e-prescribing message in Version 2.x, so it would be easy to describe any version 2 prescribing message as valid. Therefore, within a hospital for discharging prescribing, HL7 Version 2.x should be allowed, and should be required in certification.

Implementation Workgroup Chair Liz Johnson said they also suggest looking at the prescribing of controlled substances moving from menu to core in Stage 3. They would like that to be considered as a recommendation.

Halamka pointed out that the Drug Enforcement Administration (DEA) has specified standards, and it was suggested that if they make a recommendation as to controlled substances, they will have to be specific as to those standards. Steve Posnak said that CMS did include reference to controlled substance prescribing in its preamble. The ONC has explored this issue to some degree with DEA colleagues and attorneys, and it is complicated from a regulatory perspective. Dixie Baker said that e-prescribing of controlled substances requires two-factor authorization. They decided not to include it in Stage 2 because the industry is not ready for this. Halamka suggested that the Committee could simply indicate that it is a good idea.

Demographics

It was noted that a reference to "ICD10 CM" is a typo; Steve Posnak made note of this, deleting the "CM."

Jamie Ferguson said that they heard form clinicians and those working on quality issues that country of birth or nationality of patients in clinical use cases is frequently more valuable than the crude ethnicity measures that are otherwise captured for demographics. They suggest adding a data element for the nationality of a patient using the ISO 31-66-2 standard for country codes (this was recommended as an addition, not as a replacement).

Chris Chute said that from a clinical perspective, they care about identifying the country in which people received health care. Jim Walker said that the much deeper reality is that someone may have lived somewhere for 30 years, but may not have not been born there. If they want to address this, it would be a significant challenge. Perlin agreed but noted that this is a policy issue. The question is, does the Policy Committee think national identity would provide additional clinical utility. If so, this Committee could endorse a standard.

Walter Suarez pointed out that he did not hear any distinction in this discussion between country of birth and nationality. Suarez was born in Colombia, but has dual citizenship in Colombia and the United States. There is a distinction here: country of birth may be the more appropriate component, whereas nationality is a political distinction of status as a citizen of a country. Halamka said that the Policy Committee should elect what would be the appropriate field, and this Committee would have a standards recommendation to support whatever policy recommendation is made.

Floyd Eisenberg of the Clinical Quality Workgroup reminded the group that last September they sent a transmittal letter regarding quality measures for Meaningful Use. In it, with regard to the standard for preferred language, the wording they used was "ISO 639-2 constrained element in 639-1." That is slightly different from what is written in the NPRM. Jamie Ferguson concurred, and they agreed that they would recommend the wording from the transmittal letter. Also in that transmittal letter was a recommendation for CDC value sets for race and ethnicity. The Office of Management and Budget (OMB) standards are a very small subset of the CDC value set, so it will still work, but it is different from what was recommended.

Patient Engagement Workgroup Chair Leslie Kelly Hall said that patients will self-identify in very different ways, and they need to honor that. More granular descriptions of special needs are needed, as well. Chris Chute said that the task of taking note of race and ethnicity is typically assigned to the desk attendant. While the goal of self-identification is clearly desirable, as a practical matter if becomes extremely awkward.

Arien Malec brought up the issue of genetic diseases with ethnic origin. He asked Posnak, is the OMB standard considered the minimum set? What are the requirements of the EHR relative to that standard? He used the example of "white" or "Ashkenazi Jewish." What are the requirements from a meaningful use perspective? Posnak said that the OMB standard is the bucketing system. An EHR can contain a more granular set of choices, as long as that granular choice can be cross-walked to the OMB standard. Several Committee members expressed the need for more granularity, and Halamka said that Stage 3 might be the place to add that. Meanwhile, they can say that in 2014, OMB can be used, with the idea that they are signaling that they will be moving towards more granularity in the future.

Jim Walker asked where there is any published study about when a large population is asked to identify their ethnicity, how many of the 921 CMS possibilities get used. He said a reasonable hypothesis would be no more than 50. They might be making a very large commitment in terms of work and potential adverse effects by adding more granularity, and he thinks it would be smart to have an answer before they make such a recommendation. It was suggested that more research was in order by the Patient Engagement Workgroup.

Dixie Baker said that the term "granular" can have many meanings. The CDC codes are granular from two perspectives: they are worldwide and also they incorporate the source of the assertion (that is, parent race versus claimed race). Both of those are ways to be granular, so the Committee needs to be clear what on what it means by "granular."

Problem List

The Committee discussed vital signs, and Halamka said they would check last September's transmittal letter, but they do want to indicate that vital signs should be reported in a structured fashion using LOINC. It also was suggested that they broaden that to a more general statement about clinical observations generally.

The Patient Engagement Workgroup recommends the addition of a pain scale. Leslie Kelly Hall said that vital signs needs to be standardized, and patients should be able to add information from home or remote care. Another Committee member questioned whether this was the most important item to add. What about functional status, for example? They raised the basic question of how to prioritize these pieces. Hall said that they did not spend time in the Workgroup prioritizing what would be next, but pain scale would be an obvious one to share inside the hospital setting. She also suggested that they aggressively standardize the fields where the patient him or herself is a source of information. Chris Chute said that the Agency for Healthcare Research and Quality has been convening promise groups, precisely to create a consensus view as to what these kinds of patient-reported outcomes should look like. He urged that their work be carefully reviewed.

Floyd Eisenberg offered a compromise proposal. For vital signs, the question came up in their Workgroup about whether to make the pain scale a vital sign. Instead, he raised the possibility of requiring EHRs to have the capability to manage a smart form, so that those who want to use a validated pain scale, a promise scale, or a Braden scale could use whichever one they chose. The EHR would simply need to have the ability to capture information as a smart form, and calculate and store the information as a value. In the transmittal letter, some values were suggested for that: LOINC for the instrument; numerical or SNOMED for the response.

Jim Walker pointed out that this Committee's job is standards, and it is their job to say, if a pain scale is needed, this would be the standard. If the Committee does not do this, they will have a situation in which there are different pain scales that are not commensurate or comparable across time or venue.

Walker also made the general comment that there have been several transmittals to ONC that have been lost in time. Whenever they can refer specifically to a transmittal letter, it would help everyone to remember what was decided and to use that, rather than reinventing it.

David McCallie said that they were looking at a lot of list management for the clinician that may not relate to patient care. Chris Chute said that he thinks the information should be algorithmically derived. In the context of secondary data use, in which he would include clinical decision support, the ability to have aggregate categories is becoming increasingly recognized. It would be regrettable if this burden were to be put on the clinician. McCallie said he assumes that behind-the-scenes aggregation and analytics could use whatever is the appropriate tool. In

terms of something certified, unless there is a message back and forth he is not sure he is hearing a new requirement.

Mark Overhage expressed anxiety that they were adding complexity. If it can be done algorithmically, then why include it in the transmission?

Liz Johnson said they needed to be clear on the definition of longitudinal care; the recommendation was that it be based on a Policy Committee definition, with reference to the proposed rule preamble. Further, it should be patient-centric and longitudinal from multiple places. If that is the case, it may affect certification criteria for the medications list and the medication allergies list, which would make those revised rather than unchanged. Also, they must make sure testing is clear enough that certification criteria can follow.

Clinical Decision Support

Jamie Ferguson explained that the "Info Button" is misclassified as decision support. He did not suggest that it needs to be removed, but the Clinical Operations Workgroup wants to ensure that readers of the rule are not confused by its inclusion in decision support, when other things like alerts and reminders are more typically classified as decision support. Ferguson also said that there is a benefit to using info buttons in some cases, but in others simple Web links will suffice.

One Committee member said they can understand the importance of an info button in the context of documentation, but he is not sure to what policy goal this info button maps. Is there a Policy Committee recommendation that information retrieval and automated clinical decision support are both equal policy goals? Or is the Standards Committee introducing a policy need by including the standard? Halamka said that they should be able to activate a function that provides alerts, information, etc. It is hard to specify standards around alerts and reminders.

A speaker said that, to date, certification has been a functional standard, wherein some workflow triggers an alert. People do not know what to do to implement this. Dixie Baker said that the info button as a standard is not widely implemented. This Committee always look for wide implementation, and in Baker's research, she found that this is not widely implemented at this point. Another member pointed out that linking to reference literature is a widely implemented practice. If a standard can be put into place that would reduce barriers to creating those links and probably do a better job of it than typical URLs, then that would be beneficial.

Leslie Kelly Hall said that many people are using an info button inside an EHR to link to free information from NLM and other sources. In the last 3 years, there has been a dramatic shift to more info button queries than those directed by persons self-navigating.

Halamka commented that it can appear strange to call an info button decision support. It is decision support only insofar as it allows for lookup of reference materials. The overall level of dissatisfaction of alerts and reminders has lead to the search for a better way to provide information as a process evolves rather than as an interruption. They need to keep a broader definition of what decision support is.

Jim Walker asked whether it would meet the policy intention if an organization had a linked URL in its EHR that took users directly to a high-quality, evidence-based resource that was rapidly searchable. Ferguson explained that this is what the Clinical Operations Workgroup has proposed.

Mark Overhage said that there are only about five or six sources of info button servers, and not many real-world implementations in EHRs. It was implemented at his organization, and was found to be extremely tricky. It will require a nontrivial implementation effort to do it while not adversely affecting performance. It was noted that if an organization has an existing decision support in their EMR, then they will meet the functional goal of meeting decision support goals for clinicians, but they will not meet the standards goal.

Walter Suarez questioned why they were not referencing HL7's implementation guide for the info button, which might address the expectation that "yes, this is a standard and here is how to implement it." Overhage said that the flip side of saying something about the standard is the risk that there will be two ways, and another standard down the road for some other kind of decision support. Are they creating two ways of doing this? Is it either/or, or is it both? McCallie pointed out that an "or" becomes an "and" for a vendor. So, is their intent that everybody must be capable of certifying against this standard but they do not have to use it? Or, are they backing away from whether it must be done? National Coordinator for Health IT Farzad Mostashari said that the info button is clearly proposed to be required for patient-specific resources already. It is already a requirement in EHRs.

Halamka said that based on the discussion, one could say they will have a functional description of decision support without a standard. From a patient education context, an info button is great. For clinician workflow, requiring an info button may not make sense. Hall commented that the info button allows for patient-specific context, so it is a safety feature. It provides patient-specific, contextual additions for clinical decision support and patient education. If they believe that is important and material for the patient, then that should be their recommendation.

Stan Huff said that it is useful to make the distinction between something that one can read and then make a decision, versus something that applies logic and makes suggestions for a particular patient based on an algorithm. One can argue whether both are decision support, but the distinction between the two is useful.

Huff also pointed out that embedding URLs locks the user to a particular source of information. One of the goals of info buttons is to give users the option to go to a different vendor without having to change applications, etc. It creates that point of indirection so that the source can be changed without the re-engineering of all the content embedded into forms. He does not propose that they outlaw the use of URLs, but there is a real advantage, technically, to using an info button standard.

Halamka summarized the Committee's position by stating that functional criteria are best in this case. An EHR could use an info button, or it could use URLs.

Regarding configuring clinical decision support, Liz Johnson said the Implementation Workgroup has a concern that in the certification criteria, it is not clear whether a secondary alert of the physician actually making the decision happens. She referred to traditional instances of clinical decision support. It is an area not covered in the NPRM; is this the right place to add it?

It was noted that Section 4, the requirement to receive and incorporate decision support, is problematic because of workflow considerations. A physician has no control over when a transition of care comes in to him or her. Does the clinical decision support fire when the physician receives it? When he or she opens the referral, or when it gets received? There is also a legal liability concern. If a physician receives a transition of care and he or she performs the appropriate reconciliation, will the same alerts fire twice? Will legal liability occur twice?

Liz Johnson pointed out that in real time, the nurse is alerted when he or she is giving care. When is physician alerted? This is not clear in the language. Chris Chute said that the cleanest point of view is for it to fire post-reconciliation, because that is the patient that the physician is managing at that time.

Perlin said that they should not try to anticipate all of the possible ways in which an order might be mediated. He observed that care teams might share decisions. This is something that should be taken to the Policy Committee.

David McCallie cautioned Committee members about being overly specific about what these workflows look like, adding that they will evolve. The way alerts work will have to be rethought, otherwise the user will get the same information over and over again. He suggested that the requirement be just to demonstrate that an appropriate alert can be fired, but not be too much more specific than that. Hall concurred, and brought up the fact that data would be added by new participants, and added asynchronously. There will be issues about role, reconciliation, timing, and asynchronicity. Being too prescriptive will curb innovation.

Mostashari said that the question for this group is whether there is a minimum bar in terms of workflow places for trigger opportunities for decision support. Is there a minimum association with computerized physician order entry (CPOE)?

Electronic Medication Administration Record (EMAR)

Halamka said that they are not going to over-specify what technology to use. They should simply specify that clocks be synchronized. Johnson agreed, suggesting they leave open what they might be able to do. Hall suggested that the patient is a great source of self-identification. Johnson pointed out that the patient is not always able to do a self-identification. Such a requirement should not be in the rule, and may prevent care.

Clinical Summaries

Ferguson said the Clinical Operations Workgroup had a discussion about RX Norm, especially as it relates to medication-related terminology. Previously they recommended UNI for ingredient identifiers and NDFIT, but these are both now in RX Norm, as are all drug-related allergies, including contaminants in vaccines, where known.

Hall said that the Patient Engagement Team talked about allergies, but not intolerances to certain procedures—those are not accounted for in this list. She asked whether that was understood under SNOMED, or whether something else needs to be specified. Halamka said they are talking about adverse affects. Allergy is one kind of adverse affect, but there are others. An MRI would be difficult for someone with claustrophobia, for example. Steve Posnak noted that they were talking about creating policy through standards, and that this is something that should be taken back to the Policy Committee. Ferguson noted that this is another opportunity to tell the Policy Committee that, should they wish to include the topic in the clinical summary, this would be the appropriate standard.

Doug Fridsma noted that they just had the conversation about changing SNOMED from the problem list and adding administrative codes to separate those two. A similar issue exists with procedure codes, in the sense that clinical care summaries capture clinical information versus billing codes. To what degree do people make that distinction? Perhaps it is a shorthand to use billing for clinical code, but a higher-quality problem list can be created using clinical vocabulary.

Ferguson pointed back to the preamble, which indicates that the intended purpose was clinical use. That was the genesis of choosing SNOMED CT. To Fridsma's point about the desirability of adding an administrative class for procedures and devices, that may be a Policy Committee question.

Jim Walker said that an increasing number of procedures do not have an ICD code because they are not billable. A concern is that there are substantial interventions that do not have any billing implication. There is a need to capture all of those interventions, some of which simply do not have any billing code. Jamie Ferguson said that there are a number of resources available for cross-maps, subsets, and query tools related to the use of SNOMED and administrative coding systems together. There should be outreach for programmers, implementers, and users as to the availability of those resources.

McCallie said he agrees with the spirit of what they are trying to do. However, it is not possible to fully automate from SNOMED to ICD10. So, the clinician will have extra work. Like it or not, most sites do require the clinician to come up with administrative as well as clinical codes. Given the way ICD10 is coded now, most of it can be automated, but not all of it.

Patient Lists

Ferguson explained that the actual requirement for transmission relates to immunization registries, but there is a desire for an implementation guide for use of the immunization registry update standard (HL7 2.5.1) to do batch updates instead of single patient updates. Halamka noted that this is not a specific NPRM issue. Ferguson said that the Clinical Operations Workgroup has no standard implementation guide to recommend.

Mostashari said that they are often walking the line between too much specificity and vagueness. The question is whether the functionality described here captures the concept of a provider being able to do population health management. Ferguson said he thinks it is a good list, but they hear

from providers, registries, and health plans that lack of guidance for transmitting lists is a problem. Liz Johnson concurred.

Halamka said that as written, this is a good functional criteria because it allows EHRs to populate registries. Ferguson said they need an implementation guide for using the HL7 standard for this purpose. Steve Posnak pointed out that the objective is to generate lists of patients with specific conditions. The measure is one report listing of patients with a specific condition, so it is a simple functional requirement. It is a report and not a registry. Perhaps CCDA is perfectly sufficient.

Wes Rishel said that this is functional, and without a standard described about how to do it. Will that encourage many different ways to do this that will become cumbersome? Then, when Query Health comes to fruition, will it all have to be reworked? Are they adding hardwiring without adding a standard? Halamka said that this is a direction in which they want to go, but at the moment there is no well-adopted implementation guide.

Walter Suarez said that one can transmit simple lists of patients with basic demographics, but there is a very different aspect to transmitting for a specific purpose, like immunization registries. In the public health arena, a number of registries exist, and submitting data to those registries requires more than just a simple list of patients. It is a much more structured message to provide, that includes demographics and clinical information. Although there is a significant value to the list they are discussing, and it is a good first step to point to the ability to pull and transmit lists of patients, they should not mix the basic element of a list with a more complex registry message.

Patient-Specific Education Resources

McCallie said that the spirit of this goal is to make it possible to customize information to provide to the patient. He is not sure that technically narrowing it to a URL or an info button is wise. Dixie Baker said that semantic search is one of the most active areas of tech development right now, so it does not make sense to lock into specific solutions. McCallie said that the level of indirection they are adding for technical reasons could get in the way of the goal of a better-informed patient. There are many ways to get information to the patient that does not involve a link.

Posnak said that the 2011 edition of the certification criteria did not include any reference to a standard. As part of the rulemaking process, they included a standard that could advance the capability of EHR technology to provide some form of interactive educational resources. However, they could go back to the 2011 language.

Hall pointed out that this is the only standard they have that allows for bolt-ons of other technologies and applications from an EHR. It is important because they get information on all of the demographic contexts, and the opportunity to report what information the patient has received. They have been saying all along they should use standards where applicable.

Halamka said he is hearing that if products did develop around the info button, that would be good, but at the moment there are unique products that may be mobile apps. To constrain

beyond a functional criteria at the moment will stifle innovation and architecture possibilities. Yet they would like to see an ecosystem developed for the reasons Hall highlighted. Mostashari explained that on the one hand they want to raise the floor; on the other hand, there is a risk of freezing technology by defining the standards too specifically now. That is the question for this group to consider.

Halamka said it seems they are going more toward a functional desire and not a single constrained method. They could do what Stage 1 did, which is to identify functional criteria without a single named standard. Posnak said that in their regulatory tools, they have "required," and "optional" and then there is the path of not requiring anything at all. In this case, they could call it "optional," but not required to be a part of certified EHR technology. Halamka suggested that this would allow the diversity of technology and send a signal to the industry that this would be useful.

Chris Chute said they want innovation in how people exchange information; they do not want innovation in standards. A single standard would likely lead to a host of innovations. It is important as they parse this through to ask themselves, if there was a single, consistent way for external content providers to interact with an EHR, would they see a decrease in cost to getting access to patient material and provider information? Standards do not necessarily constrain innovation, but rather can promote innovation.

David McCallie came back to the notion of mobile devices and emerging technology having to do with the way people manage their information. He thinks "optional" makes great sense.

Transitions of Care

Jamie Ferguson began by saying that Consolidated CDA is very advantageous. For transport, the Clinical Operations Workgroup feels that both SMIME/SMTP and SOAP should be equally required. Providers should choose among those standards which one best fits their community, their referral patterns, and so forth. As a result of more recent conversations, he struck the last two sentences of the Workgroup's recommendation #2, which addresses non-standard approaches. Instead, because different protocols fit different scenarios, they would recommend allowing either Direct or Exchange to be used. In response to comments by Halamka, Ferguson said that the gist of the Workgroup comment is that, by requiring both SOAP and SMTP in certification, the provider then has the choice of what best suits their situation.

The Implementation Workgroup drew similar conclusions. It noted that CMS requested further definition of a care plan, and they ran out of time. This is a need. They also had other comments related to the issue of additional known care team members. There should not be a requirement unless they know what a "care team" means. The Workgroup also discussed the need for more clarification around which transport standards apply to which domains.

Wes Rishel said he is concerned about what happens when a standard is changed. If one hospital is using software that is on version A of the standard, and they communicate with another hospital that uses version B of the standard, then neither can go until the other has proceeded. In U.S. health care, the change from the 4010 to the 5010 X12 standards recently occurred. It was a big effort, with lots of money spent, even though the changes were rather minor. It happened

almost 10 years after the 4010 went mandatory, and fixed problems that were known when 4010 went mandatory. On September 30, the old standard was used, and on October 1, claims used the new standard. Everyone had to be ready and had to move over on the same day. One major payer, who provides most of the funding for senior care in the United States, had an error in its cutover and it caused a large slip in deliverables due to false rejections. It was corrected fairly quickly, but there was collateral damage.

Rishel's goal is to find a way, as they move standards forward, to cut over to a new standard from an old one bilaterally, not at the same time. There is good evidence on how to do that from the Internet. E-mail went from plain text to the ability to send pictures as an attachment, to having pictures right in the e-mail. Framers of the interface accounted for bilateral asynchronous cutover in their interface definition. They said, "if someone wants to send a multimedia message, fine, but they must send the plain text message, too." Fundamentally, a receiver receiving a message according to an older version of the standard needs to know how to process it. Ideally, it looks mostly like before but with some data missing, or some data that is in a different place. The receiver of the new message must have a defined behavior for receiving the old message, most of which can be done with the syntax. If they put such standards in place, and write certification criteria that actively enforce these behaviors, that will put them in a good position when new definitions of standards are released.

Dixie Baker pointed out that the reference relating to SOAP in the specification is not to the entire set of exchange standards; it is only to the part of NwHIN relating to the standards and interoperability framework modular version of the exchange platform standard, version 1.0. It does not include the other exchange standards. At one place it requires Direct, and does not mention the others. They must be consistent. She also said that the reason Direct standards were brought about was to allow the little guy to exchange. She asked, if they now impose SOAP on the little guy, then what is the point of doing this?

Arien Malec said that the intent of the Direct Project was to create a way to send a message without negotiating all of the SOAP "hops." If everyone is connected to Exchange, it can be done that way. The intent, though, was to decouple the single trust network and still allow for universal transporting. Their recommendation in Direct was that SMTP and SMIME was required, and because many support the XDR standard, that EHRs should be able to plug into a module, generally a health information service provider (HISP), that would be under a Business Associate Agreement (BAA) to plug into a capability that does the upgrade or downgrade. The intent was to support EHRs at their given level of understanding, inclusive of EHRs that want to do basic activities, and EHRs that have the full implementation of XDR. That is why the recommendation was for SMTP/SMIME to be required with a well-defined path.

Halamka asked, how can they be sure that there is not a mismatch between protocols and versions? The challenge is to not constrain architecture. Some communities may have an HISP, and other may not; there are all kinds of possibilities. The Direct Project made SMTP/SMIME mandatory and XDR optional and showed how to support it for those who have it. That statement may not work in every community implementation, and that is the concern.

McCallie said that the goal of Direct was to enable the notion of universality with a minimum secure trust model, so that it was likely and easy for all providers to communicate without requiring additional negotiations, other than membership in a trust community. It would be a shame if they lost that goal. On the other hand, those using a more complicated protocol should get credit for meaningful use. So, he recommended certifying to the minimum but giving credit to everything above that, if a provider is achieving the incentive goal.

Mostashari asked whether two vendors could use SOAP to communicate and get meaningful use credit for it, if SOAP was optional. Steve Posnak said yes, they would, because today's proposed language says that providers must use certified technology. That is supported by requiring the Direct specification and allowing EHR vendors, depending on the market, also to get certified to SOAP options. If a customer wants to speak SOAP, they can use that certified technology to demonstrate meaningful use.

Halamka asked whether reference to SOAP is even needed. A Committee member said that they have all agreed they should take out SOAP because it does not mean anything in this context. David McCallie interjected, saying it means something on the wire. The Direct adapter takes the XDM content out of XDR, and puts it on top of SMTP, so it is SMTP on the wire. On the wire is where the interconnection actually happens.

Baker said it is important to be clear that they are talking about transport, and not the entire exchange stack. She said they should not specify either SOAP alone or the entire exchange stack. It was suggested that some sort of schematic would be useful to help demonstrate the multiple ways in which organizations can interact.

One Committee member said they think it is a fair statement that the marker CMS has put down has catalyzed the market. The work is not complete, but some clarity about the specificity may be enough. There was skepticism about this 6 months ago, but no longer.

Wes Rishel said that he sees nothing in the 2014 edition that even provides a base level of support for the process of getting a sufficiently meaningful trust certificate. However, he takes great faith in the 10% number and in the fact that most institutions can meet that 10% by working with other institutions that they know and do business with regularly. In which case, the process for trading certificates is handled in Direct. That bar cannot be raised until some of the other planned work gets further down the path.

Mark Overhage said that none of the standards that have been discussed will magically solve the trust and identity problem, and so the need to have a local community define sufficient trust for directed exchange is going to be a prerequisite for the 10%; the standards will not get them there. They will be forcing the problem on local communities to solve this definition of trust and identity. Left to their own devices they may solve it poorly, insufficiently, or incompatibly. They must set the appropriate expectations and have well-defined policy, especially for identity.

At this point, Perlin moved to a consent agenda for working through the remaining items. He said they would assume that these have been litigated in each of the workgroups, and asked that Committee members only speak if they have a very significant objection.

One committee member asked about demographic variables used to link individuals. The rationale was around patient safety. He asked if there would be an opportunity to discuss the practice of comparing this payment that one based on name, date of birth, etc. Halamka said that Mark Overhage's team recommended a set of demographic elements, and the header was included in a discussion with the Privacy and Security Workgroup. Steve Posnak said that the Privacy and Security Tiger Team has that charge and they are working on it.

Transmission of Electronic Lab Standards

Liz Johnson said that if the Policy Committee needs them, the Implementation Workgroup has defined parameters for numerators and denominators for standards. Malec said that the Policy Committee is reconsidering this one. As a receiver, it is easy to receive LOINC where it has been provided. As a sender, anything that is not LOINC is not counted, and that is problematic. A sender may have appropriate LOINC coding for the most frequently sent lab codes, but there may be some particular tests that have not yet been mapped to LOINC. It could be important from a meaningful use perspective to look at those cases and make sure there is flexibility.

View/Download/Transmit to a Third Party

Jamie Ferguson referred to bottom half of page 16, and a comment that was developed by the Clinical Operations Workgroup, suggesting that the patient download capability should be required to use the Consolidated CDA format. This can meet all the objectives of individual empowerment for view/print/download/re-upload, and also has the benefits that free text does not have—being able to reuse data by integrating into other systems.

David McCallie noted that this may not be the case. He suggested that people not be required to use it, but that it be made available. The concern is that there may be content in the record that is downloadable but does not yet fall into the CDA specification. For example, a stand-alone image is not technically CDA. Halamka suggested that they should be defining a floor; McCallie agreed.

Baker pointed to TLS as a criterion that specifically addresses the need to create a secure channel for viewing and downloading. It is very similar to the criteria for transmitting to a third party, but where transmission to a third party can use Direct, viewing and downloading cannot. TLS is appropriate for viewing and downloading. Steve Posnak suggested adding language that would make TLS optional.

It was noted that on pages 19-20, "audit log must not be capable of being changed, written, deleted" appears. Regulations require the destruction of audit logs after a period of time. Also, the requirement says that an EHR must be impossible to change or delete. The requirement also indicates that it must be able to detect changes. If it is impossible to modify, then why should the vendor be required to track something that can never happen?

A speaker pointed to page 26, where the language indicates that the EHR must only be permitted to be disabled by a limited set of users. It was suggested that they make sure this is not implying the capability to disable it. They could add "if permitted," to indicate that it may only be possible for a limited set of identified users to disable it, as a test method. The Committee

member asked why they would want such a function. Halamka suggested they either strike the whole thing, or say that if it may be disabled, then it should be only disabled by authorized users.

Family History

A discussion took place about the different standards that could be applied to family history, and Halamka suggested that they add language making the Surgeon General's XML optional. Mostashari said that this is one of a few areas in which new criteria were added to meaningful use. The Policy Committee, in its deliberations about whether the measure should be kept or not, suggested that one of their criterion was whether a widely adopted standard exists.

Jim Walker said that there are elements of family history that are parts of validated clinical prediction rules that could be used meaningfully to identify a patient's risk for having diseases. Those family history elements are extremely precise, and if they are not captured with that precision then the clinical prediction is not valid. So this is a Policy Committee issue, but he recommended that they invite the Policy Committee to consider identifying a standard that could actually be used meaningfully, as opposed to one that may have a wide user acceptance but cannot actually be translated into anything that would be useful for the patient.

Clinical Quality Measures

Floyd Eisenberg said the Clinical Quality Workgroup had a lot of discussion about the quality data model (QDM). Issues around QDM are that it was developed based on the need for information for quality measures. In the process that occurred in the retooling of e-measures, there were many areas of metadata that had to be expressed, some of which are not in the meaningful use certification requirements. There is not a direct one-to-one match. He suggested some methods to manage that, and he also raised the option of not discussing the QDM at all, but just the components needed to express the measure.

It was pointed out that a provider would only need to certify to this requirement if they intended their EHR to be useful for cancer menu item. Mostashari said that this is an important point, a new approach to certification: certify only what is needed for meaningful use when there are menu items. That makes the bar a little bit lower in terms of including certification requirements.

Wes Rishel said that with regard to bilateral asynchronous cutover, he has specific recommendations he did not present here, but would like to present them by e-mail in order to have the opportunity to include them in the letter.

Perlin asked Rishel to get the letter out to the Committee. Notwithstanding that singular item, Perlin asked for and received consensus on the recommendations that would be transmitted, as modified in real-time by Steve Posnak.

> **Action Item #2:** The Committee accepted by consensus the information in the HITSC Comments on ONC Standards and Certification Criteria NPRM (and CMS MU Stage 2 NPRM) grid, as modified during the meeting by Steve Posnak.

6. Patient Engagement Power Team Comments

Leslie Kelly Hall presented a slide deck that began with the new Patient Engagement Power Team's charge and team members. She said that in determining how standards might meet patient engagement, the Team came up with some overarching themes and comments, addressed in the slides. Where policy exists and standards do not, they would like to see the potential for most EHR actions and reactions in a patient-facing system. She suggested, then, that they look at "two-fers" where there are gaps in the standards, and address the patient-facing issues while solving existing gaps. The group's overarching guideposts are as follows:

- Nothing about me without me: CC:ME
- I am a contributing care team member: Patient generates as well as receives data
- Many EHR actions have a patient-facing system reaction: Patient orders
- Patient-facing systems are not limited by legacy systems: API
- How does my care compare? Patient report cards.

Hall talked about the high level of energy and enthusiasm that this group has generated, and said that there would be value in extending this type of effort across both the Standards and the Policy Committees, jointly or in collaboration. The Power Team also produced a detailed grid in response to the NPRM, which was included in the meeting materials.

Discussion

Farzad Mostashari said that the "CC:me" example that Hall presented as an overarching principle is an example of how a potentially interesting standard might provide possibilities to policy. Dixie Baker said one topic that frequently comes up no matter what they are discussing is the enormous challenge that the industry has with regard to patient identity and assuring the accuracy of patient identity. Baker believes that a Patient Engagement Workgroup would be an ideal body to take that on.

Another Committee member said that patients who have considerable health needs tend to value care over some of the very legitimate privacy and security concerns, and welcomed a dialog where there is some optionality for people to choose. All policy and technology is directed towards trying to solve something for which there is another approach. The group used the phrase, "the data should be provider protected and patient directed." In that way, the user can be identified, but everyone understands that, as adults, people have the right to choose what to do with their own data after they download it.

Speaking as the person at ONC who is responsible for consumer health activities, Jodi Daniel said this thinking is extremely helpful. Even if there are some challenges to immediate implementation, some of this is incredibly forward thinking. Having these ideas and conflicts on the table to help shape policy thinking is incredibly valid and useful. She encouraged Committee members to continue these discussions, and said they would talk internally about how ONC can support ongoing efforts.

Perlin described Hall's presentation as the capstone to the day, a milestone in itself because of the progression of thinking and engagement around patients as partners, and also in terms of the capability for them to contemplate patient-inclusiveness in the context of meaningful use.

Halamka concluded the day's discussion by saying they had come up with a very parsimonious set of standards.

7. Public Comments

Lindsey Hagel from the Academy of Nutrition and Dietetics thanked the Committee for addressing their concerns about food allergies. They consider food allergies to be a critical clinical issue, and Hagel expressed appreciation for the Committee's handling of this topic. One critical patient safety issue remains: inpatient diet orders. Hagel looked for use cases to share, and could not find any to address the subject, which she said is not uncommon. In the inpatient setting, it is required that a care provider write a diet order before a patient can be given anything to eat. Mishaps are not well documented, she said, but are well known. Some examples of this include patients being given food when they should not have been because of scheduled surgery; dysphasia patients (who have difficulty swallowing) being put on a regular diet; renal patients not being provided a low-potassium diet; and several others. Hagel asked that the Committee prioritize clinical critical data, which includes diet, prior to some of the more burdensome tasks and requirements for Stage 2.

Carol Bickford from the American Nurses Association thanked the Patient Empowerment group for their presentation. She challenged ONC to make their message available to those who stepped up to the plate in the "Putting the 'I' in Health IT" program, and in their media outreach. Also, she urged the Committee to visit the National Committee on Vital and Health Statistics (NCVHS) Web site and review testimony and recommendations regarding patient identification.

SUMMARY OF ACTION ITEMS:

Action Item #1: The Committee approved the minutes of the March 27, 2012 HITSC meeting by consensus.

Action Item #2: The Committee accepted by consensus the information in the "HITSC Comments on ONC Standards & Certification Criteria NPRM (and CMS MU Stage 2 NPRM)" grid, as modified during the meeting by Steve Posnak.